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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

EUGENE DIVISION

BETTY PHELPS and **DELBERT PHELPS,**	**CASE NO: 3:09-CV-6168-TC**

Plaintiffs,

VS.

WYETH, INC.,
SCHWARZ PHARMA, INC.,
PLIVA USA, INC.,
NORTHSTAR RX LLC, and
ALAVEN PHARMACEUTICAL, LLC.

Defendants.

PLAINTIFFS BETTY AND DELBERT PHELPS' CONCISE STATEMENT OF FACTS IN OPPOSITION TO PLIVA, INC.'S MOTION FOR SUMMARY JUDGMENT

In response to defendants PLIVA, Inc.'s Motion for Summary Judgment, Plaintiffs Betty and Delbert Phelps state as set forth below.

I. INTRODUCTION

In its Motion for Summary Judgment, PLIVA, Inc. ("hereinafter referred to as "PLIVA") asserts several bases for granting summary judgment in favor of Defendant. Specifically, the grounds identified in PLIVA's motion are as follows:

1. Plaintiffs' claims are time barred;
2. Plaintiffs cannot establish general or specific causation;
3. Plaintiffs cannot establish that PLIVA's alleged failure to warn proximately caused Mrs. Phelps injuries;
4. Plaintiffs have not met their burden on their defective design claim;
5. The learned intermediary doctrine bars plaintiffs' Negligence claim;
6. Plaintiffs cannot meet their burden of proof on their gross Negligence claims;
7. Plaintiffs have not met their burden on their warranty claims;

8. Plaintiffs have not met their burden on their misrepresentation and fraud claims ;

9. Plaintiffs have not met their burden on their punitive damages claims.

In its brief, PLIVA mischaracterizes the relevant facts and misstates the applicable law, and for that reason, their motion should be denied.

II. LAW AND ARGUMENT

A. Plaintiffs Have A Cause Of Action Under Oregon Law

In its Motion, PLIVA asserts that Plaintiffs have no cause of action under Oregon law for the manufacturer's failure to instruct prescribers and consumers on the proper use of its drug products, and for failing to warn against dangerous uses of its metoclopramide products. In particular, PLIVA argues that O.R.S. §30.900 does not encompass a claim against the manufacturer for failing to indicate that metoclopramide therapy should not exceed 12 weeks in duration, for failing to provide instructions on how metoclopramide should be used in geriatric patients, or for failing to inform physicians and consumers that metoclopramide is a neuroleptic – a class of drugs well-known to cause movement disorders. A simple reading of the text of O.R.S. §30.900 refutes the argument advanced by PLIVA:

> As used in ORS 30.900 to 30.920, "product liability civil action" means a civil action brought against a manufacturer, distributor, seller or lessor of a product for damages for personal injury, death or property damage arising out of:
>
> (1) Any design, inspection, testing, manufacturing or other defect in a product;
>
> (2) Any failure to warn regarding a product; or
>
> (3) Any failure to properly instruct in the use of a product.

Plaintiffs' claims against PLIVA do not arise as a result of duties imposed by federal law as the Defendant claims, but rather arises from well-established Oregon law. The fact that federal law limited the actions that PLIVA could take to alert prescribers and consumers of important safety information about metoclopramide does not excuse it for its failure to take *any*

action. In essence, PLIVA argues that since it had no authority to strengthen its warning, it had no duty to act reasonably under the circumstances. As Oregon courts have held, that stance is plainly wrong. *Peterson v. Multnomah County Sch. Dist. No. 1*, 668 P.2d 385, 392 (Or. App. 1983).

In Oregon, manufacturers of prescription drugs have the duty to make "timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs of which it knows, or has reason to know." *Allen v. G.D. Searle & Co.*, 708 F.Supp. 1142, 1148 (D. Or. 1989), quoting *McEwen v. Ortho Pharmaceutical Corp.*, 528 P.2d 522, 528 (Or. 1974). The drug manufacturer is under a continuous duty to keep abreast of scientific developments regarding the safety of its product and to notify the medical profession of any additional side effects discovered from its use. *McEwen*, 528 P.2d at 528. The drug manufacturer's duty to warn is, therefore, commensurate not only with its actual knowledge gained from research and adverse reaction reports but also with its constructive knowledge as measured by scientific literature and other available means of communication. *McEwen*, 528 P.2d 522, 528-29 (Or. 1974).

The duty of the ethical drug manufacturer to warn extends to all members of the medical profession who come into contact with the patient in a decision-making capacity. *Id* at 529. To satisfy this duty, the manufacturer must utilize methods of warning which will be reasonably effective, taking into account both the seriousness of the drug's adverse effects and the difficulties inherent in bringing such information to the attention of a group as large and diverse as the medical profession. *Id; see also Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969). The warning should be sufficient to apprise the general practitioner as well as the 'unusually sophisticated medical man' of the dangerous propensities of the drug. *Id*, citing

Parke-Davis & Co. v. Stromsodt, 411 F.2d 1390, 1400 (8th Cir. 1969). In short, 'it is incumbent upon the manufacturer to bring the warning home to the doctor.' *Id.*

Because the ethical drug manufacturer has only the duty to warn the medical profession of those adverse effects of which it knows, or has reason to know, the adequacy of the warnings given by each defendant depends upon the actual and constructive knowledge of that defendant before and during the period in which the plaintiff used its drug. *McEwen,* 528 P.2d at 530. Furthermore, a plaintiff may recover from a manufacturer for physical harm caused by its product if it negligently fails "to take appropriate steps to warn" a plaintiff of such characteristics. *Barry v. Don Hall Laboratories*, 642 P.2d 685 (Or. App. 1982); *see also Harris v. Northwest Natural Gas Co.,* 588 P.2d 18 (Or. 1978). Furthermore, the action that may render a manufacturer liable for a consumer's injuries is *supplying* the product without an adequate warning – not failing to provide a different or additional warning than was actually given. *See* ." *Glover v. BIC Corp*., 6 F.3d 1318, 1323 (9th Cir. 1993); citing *Anderson v. Klix Chemical Co.*, 256 Or. 199, 202, 472 P.2d 806, 808 (1970). As stated by the 9th Circuit, under Oregon law "[i]n order to prevent the product from being unreasonably dangerous, the seller may be required *to give directions or warning, on the container,* as to its use. *Id.;* quoting Restatement (Second) of Torts § 402A cmt. 3 (1965) (emphasis supplied).

In addition, Oregon recognizes the doctrine of negligence *per se,* which establishes provides that a statute or regulation may serve as the standard of care a party is required to meet. In order to state a claim for negligence *per se*, it must be alleged that (1) the defendant violated a statute; (2) plaintiffs were injured as a result of that violation; (3) plaintiffs were a member of the class of persons meant to be protected by the statute; and (4) the injury plaintiffs suffered is of a type that the statute was enacted to prevent. *McAlpine v. Multnomah County*, 131 Or.App. 136,

883 P.2d 869, 873 (1994), *see also, McDonald v. Sun Oil Co.*, 423 F.Supp.2d 1114, 1127-28 (D.Or. 2006). Furthermore, an agency's regulations have the same force and authority of law, and a violation of an FDA regulation constitutes a violation of the FDCA *per se*. *Kehdi v. BNSF Ry. Co.*, 2007 WL 2994600 at *3, (D.Or. 2007), *citing Lilly v. Grand Trunk R. Co.*, 317 U.S. 481, 488 (1943); *see also Dyer v. United States*, 832 F.2d 1062, 1065 (9th Cir. 1987). Oregon courts have explicitly held that a plaintiff may allege a cause of action against a drug manufacturer under the doctrine of negligence *per se* for failing to comply with FDA regulations. *Axen v. American Home Products Corp. ex rel*, 974 P.2d 224 (Or.App. 1999). Here, there is no dispute that PLIVA was in violation of numerous FDA regulations (in addition to the FDCA itself), and Plaintiffs were injured as a result of these violations.

Finally, contrary to the arguments presented in PLIVA's motion, Oregon law provides for recovery against the manufacturer for concealing information that it had a duty to disclose. *See Est. of Schwarz v. Philip Morris Inc.*, 135 P.3d 409, 422 (Or. App. 2006) *aff'd sub nom. Est. of Schwarz ex rel. Schwarz v. Philip Morris Inc.*, 235 P.3d 668 (Or. 2010) *adhered to on reconsideration*, 246 P.3d 479 (Or. 2010) (manufacturer may be held liable for failing to disclose information to public); *Peterson v. Multnomah County Sch. Dist. No. 1*, 668 P.2d 385, 393 (Or. App. 1983) (breach of duty may occur by negligent failure to perform as well as negligent performance).

It is apparent that PLIVA believes there are no set of facts or circumstances that would subject it to liability. No court has found this to be the case, and the laws of Oregon state precisely the opposite. PLIVA's argument that Oregon law does not provide a remedy under the facts of this case is without merit.

B. Plaintiffs Do Not Allege PLIVA Should Have Provided An Inadequate Warning

In its Brief, PLIVA also asserts that Plaintiffs' claim must be dismissed because there is no duty to communicate an "inadequate" warning. PLIVA's argument fails to recognize a critical element of the allegation at issue. Specifically, PLIVA's argument does not take into consideration the *manner* in which Plaintiff alleges PLIVA's warnings relating to metoclopramide were inadequate. PLIVA simply assumes that the inadequacy alleged is with respect to the *content* of the metoclopramide label – but that is not the only manner in which a drug's warning or label can be inadequate. As shown below, PLIVA's argument lacks merit, because Plaintiffs have alleged, and provided proof that the warning PLIVA provided was not only inadequate because it failed to contain information added to the RLD in 2003 and 2004, but also because that information had not been communicated to the medical community or consumers.

The proposition that a manufacturer owes a duty not only to draft a warning whose content is adequate, but also to undertake reasonable efforts to communicate that warning to those who are likely to need it has been "well-established." *See U.S. v. State of Washington,* 351 F.2d 913, 916 (9th Cir. 1965); citing *Indian Towing Co. v. United States*, 350 U.S. 61, 69 (1955); *see also,* Memorandum in Support of Plaintiffs' Motion for Reconsidertion, [Doc. 299, pp. 8-16]. As shown above, the duty to communicate warnings applies with equal force to pharmaceutical manufacturers.

Plaintiff has shown that PLIVA's warnings and directions regarding metoclopramide were inadequate because the manufacturer did not communicate to physicians or consumers (1) that use of metoclopramide should not exceed 12 weeks in duration, (2) information necessary to safe use of the drug in geriatric patients, and (3) that metoclopramide was a neuroleptic, with the

same propensity as other neuroleptics to cause tardive dyskinesia. As provided in Plaintiffs' Concise Statement of Material Facts, no manufacturer published or disseminated any labels or warnings for Reglan or metoclopramide after 2002, with the result that the only information provided to physicians lacked the information added in 2003 and 2004.[1] As a direct result of PLIVA's failure to communicate this information, the entire metoclopramide prescribing and consuming community, including Mrs. Phelps and her physicians, remained unaware that the drug should not be used for longer than 12 weeks. This is the how PLIVA's warning for metoclopramide remained inadequate until 2009.

Under this scenario there is no inconsistency in the allegation that the warning remained inadequate until 2009 and the assertion that PLIVA should have communicated the warnings added to the label in 2003 and 2004. The failure to communicate this additional information is precisely the reason why the warning remained inadequate in the first instance (i.e. PLIVA failed to inform prescribers that "therapy with metoclopramide should not exceed 12 weeks in duration"), so PLIVA's communication of this additional information would have remedied the alleged inadequacy.

PLIVA's argument also completely ignores another fundamental tenet of Oregon law - under ordinary circumstances a plaintiff's subjective determination of a warning's adequacy does not resolve the issue of adequacy. Rather, according to the learned intermediary doctrine, it is the information provided to the individual's prescribing physician that typically determines the adequacy of the warnings provided for a prescription drug. "Under the 'learned intermediary'

[1] PLIVA asserts that that Plaintiff's claims against it for failing to communicate warnings added to the label in 2003 and 2004 are inconsistent because Plaintiff alleged that her physicians relied on information publdished by the brand manufacturers. There is no such inconsistency – Plaintiff alleges that her physician relied on information distributed by the Brand Defendants *prior to* the addition of the 2003 and 2004 warnings. Like PLIVA, the Brand Defendants made no effort to disseminate updated labels for metoclopramide after 2002.

doctrine, a manufacturer of a prescription pharmaceutical product satisfies its duty to warn of the risk associated with the use of that product if it communicates adequate warnings to the prescribing physician." *Griffith v. Blatt*, 973 P.2d 385, 388-89 (Or. Ct. App. 1999). Even with its herculean effort to spin the facts and law in its favor, PLIVA does not deny that it never provided any information about metoclopramide (let alone the information added in 2003 and 2004) to any physician, ever.[2] There can be no other conclusion than that PLIVA breached its duty to communicate adequate warnings to the medical community.

C. *Buckman* is Inapposite

In its Motion, PLIVA also asserts that its failure to incorporate warnings and information added to the metoclopramide RLD label during the time that Mrs. Phelps was consuming the drug is immaterial, as any claim considering this failure would be preempted under the Supreme Court's decision in *Buckman v. Plaintiffs' Legal Comm.,* 531 U.S. 341 (2001). PLIVA's argument completely misunderstands the Court's analysis and the issues decided in *Buckman*.[3]

The issue before the Court in *Buckman* was whether a plaintiff could assert liability against an individual who owed him no traditional state law duty based on fraudulent representations made by that party to the FDA. While finding that the plaintiff could not proceed on these so-called "fraud-on-the-FDA" claims, the Court distinguished such claims that arise from traditional state tort law principles, stating that the latter sort did not rise solely from the violation of provisions of federal law. *Id.* at 352. The Court stated that although certain state-

[2] PLIVA willfully misconstrues Plaintiffs' claims by arguing that proximate cause cannot be proven because neither Mrs. Phelps nor her Physicians ever relied on PLIVA's labeling. PLIVA's argument proves Plaintiffs' point – no one *could* rely on their label, because they never provided it. In any event, PLIVA's depiction of Oregon law is incorrect – reliance on a drug label is not required to prove proximate causation in cases such as this.

law causes of action which "parallel" federal safety requirements would not be preempted, it could not be said that *any* violation of the FDCA will support a state-law claim. *Id.*

As shown above, Plaintiff has not alleged any causes of action that are based solely on a violation of federal law, but rather only traditional state law tort causes of action. While PLIVA argues that Plaintiff failed to identify any provision of Oregon law that would require the manufacturer to add or communicate warnings against long-term metoclopramide use, or provide accurate and/or adequate information in the label for its drug, there is simply no support for such proposition. PLIVA's argument that Plaintiffs do not have standing to assert their claims under *Buckman* because the FDA does not authorize a private right of action is a desperate attempt to grasp at straws. The argument PLIVA advances is directly refuted by the U.S. Supreme Court's decision in *Wyeth v. Levine,* 555 U.S. 555 (2009), where the Court found a brand-name manufacturer liable for failing to provide an adequate warning for its drug product – as required by both state and federal law. That decision cannot be squared with the argument presented by PLIVA. The Court specifically rejected the argument advanced by PLIVA here, finding reliance on *Buckman* "especially curious, as that case involved state-law fraud-on-the-agency claims, and the Court distinguished state regulation of health and safety matters to which the presumption [against preemption] applies." *Id.* at 565, n.3. The Supreme Court recently reaffirmed this stance by stating that *Buckman* is applicable only to "uniquely federal areas of interest" and inapplicable to areas usually occupied by the states. *See Chamber of Com. of U.S. v. Whiting*, 131 S. Ct. 1968, 1971 (2011).

Finally, numerous appellate courts have determined that *Buckman* does not preempt claims such as Plaintiff's in the present case, and despite being given the opportunity to do so, the Supreme Court has not determined otherwise. *See, e.g., In re Pharm. Indus. Average*

Wholesale Price Litig., 582 F.3d 156, 176 (1st Cir. 2009); *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 86 (2d Cir. 2006) *aff'd sub nom. Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008); *Zahl v. Harper*, 282 F.3d 204, 212 (3d Cir. 2002); *Bass v. Stryker Corp.*, 669 F.3d 501, 514 (5th Cir. 2012); *Bausch v. Stryker Corp.*, 630 F.3d 546, 557 (7th Cir. 2010) *cert. denied*, 132 S. Ct. 498 (U.S. 2011); *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935, 944 (8th Cir. 2011); *Levine v. Wyeth*, 944 A.2d 179, 187 (Vt. 2006) *aff'd*, 555 U.S. 555 (2009).

D. The Authority Cited By PLIVA Does Not Support Its Position

PLIVA also argues that Plaintiff's claims are preempted by relying on briefing and correspondence transmitted to various courts. *See* [Doc. 302, pp. 23-26]. In addition to mischaracterizing the issues that were before the courts whose decision it cites, PLIVA's argument has absolutely no basis in basic legal principles, as briefing submitted to courts does not constitute precedent or authority, and provides no assistance to this Court.

Ordinarily, a district court has no authority to re-examine an issue settled by a superior court. *See U.S. v. Castellanos*, 608 F.3d 1010, 1016-17 (8th Cir. 2010). The proscription on reexamination covers only those issues decided by an appellate court, however, and does not encompass issues that could have been raised, but were not ruled upon. *Cooper Industries Inc. v. Aviall Services, Inc.*, 543 U.S. 157 (2004) ("Questions that merely lurk in the record, neither brought to the attention of the court, nor ruled upon, are not to be considered as having been so decided as to constitute precedents"). While a higher court's decision is controlling as to matters within its compass, the lower court remains free to decide other issues not considered by the court above. *Castellanos* at 1017; citing *Sprague v. Ticonic Nat'l Bank*, 307 U.S. 161 (1939).

The same reasoning applies when applying controlling precedent -- while lower courts are constrained to follow the opinions of a superior court that are "directly controlling," they

remain free to determine issues that were not addressed by that authority. *See Agostini v. Felton*, 521 U.S. 203, 237 (1997). Lower courts are only obliged to adhere to a superior court's determinations with respect to issues that the court previously determined. *In re Sanford Fork & Tool Co.*, 160 U.S. 247 (1895). Where the superior court has left issues unresolved, the lower court "may consider and decide any matters left open by" the superior court's previous rulings. *Id.* at 256. As none of the appellate courts cited by PLIVA in its motion made even the slightest mention of the issues before this Court, the argument rests, not on shaky ground, but no ground at all. PLIVA's assertions are not valid legal arguments, they are instead an invitation to opine as to what went on in the minds of judges who may or may not have considered the arguments advanced.

E. Plaintiffs' Injuries Were Caused By PLIVA

As mentioned above, PLIVA also argues that Plaintiffs cannot establish proximate cause because there is no evidence that Mrs. Phelps or her doctors read PLIVA's label. As illustrated above, it was the fact that the information appearing in the FDA-approved label was unavailable to Plaintiff and her Physicians that rendered PLIVA's warning inadequate. In any event, contrary to PLIVA's assertion, reliance is not an element of Plaintiffs' claims. To be sure, Oregon does not require reliance upon a label or warning (or even that it read) in order for liability to attach. *See Benjamin v. Wal-Mart Stores, Inc.*, 61 P.3d 257, 267 (Or. App. 2002) (an unread warning may still be found inadequate).

Plaintiffs can easily prove proximate causation by demonstrating that the chain of events resulting in Mrs. Phelps's injuries would have been interrupted had a proper warning been provided. S*almon v. Parke, Davis and Co.*, 520 F.2d 1359 (4th Cir. 1975). Plaintiff can easily provide proof of proximate cause in this manner. Dr. Phuntshog, and Dr. Chamberlain, the

physicians who prescribed metoclopramide to Mrs. Phelps for gastrointestinal issues, each testified in their depositions that they were now aware of the dangers of prescribing metoclopramide for durations beyond 12 weeks, and that they were unaware of them at the time they prescribed the drug to Plaintiff. (Plaintiffs' Concise Statement of Material Facts, ¶¶7-10,12,14). Furthermore, both testified that had they known that metoclopramide should not be used long-term, that they would not have prescribed Mrs. Phelps the drug. *Id.* Clearly, Plaintiffs can provide evidence that had PLIVA corrected its label to state that therapy with metoclopramide should not exceed 12 weeks in duration, that it is a neuroleptic, or that it must be used with caution in elderly patients, that Mrs. Phelps' injuries could have been avoided. (*See also* Phelps Dep., Ex. 1, pp. 130-31) (Plaintiff wishes she had known that metoclopramide could cause tardive dyskinesia because it would have saved her a lot of grief).

F. Plaintiff Has Rebutted The Presumption In O.R.S. §30.910

PLIVA asserts that Plaintiffs' claims are barred because "it is undisputed that Mrs. Phelps' use of metoclopramide for a period of more than 12 weeks was an off-label use of the product. Nothing could be further from the truth – in fact, the only testimony of record regarding what Mrs. Phelps' physicians knew at the time they prescribed her metoclopramide unequivocally indicates that they did **not** understand use of metoclopramide for longer than 12 weeks to be an off-label use.[4]

Initially, PLIVA blatantly attempts to mislead the Court with its assertion that Dr. Phuntshog testified that "when he prescribed Reglan to Mrs. Phelps for a period longer than 12 weeks starting in April 2004, he understood that he was using the medication for an off-label use…" (PLIVA Memorandum at pg. 28). In fact, Dr. Phuntshog did not state that he understood

[4] In addition, the FDA defines "intended use" as any use that its manufacturer "knows, or has knowledge of facts that would give him notice" is occurring 21 C.F.R 201.128.

his long-term prescription was off-label ***when he wrote the prescription.*** Rather, Dr. Phuntshog was provided with the 2004 FDA-approved label (which was never provided to any physician), and asked if his prescription of metoclopramide six years previously was outside the duration of therapy limits described within. PLIVA has not been candid with its representation of the facts. In fact, Dr. Phuntshog testified that while he ***now*** knows that long-term use of metoclopramide is unsafe and prohibited by the label, at the time he was prescribing the drug to Mrs. Phelps, he was unaware of any restriction on long-term use, and did not believe that he was prescribing metoclopramide off-label. (Plaintiffs' Concise Statement of Material Facts, ¶9).

There is also no support for PLIVA's contention that the pre-2004 metoclopramide also limited use of the drug to 12 weeks or less. Once again, this statement is directly refuted by the testimony of Schwarz Pharma, Inc.'s corporate representative, the manufacturer of brand-name Reglan, and the entity that made the 2003 and 2004 label changes. According to Schwarz, prior to the addition of language in 2004, prescribing the drug for longer than 12 weeks was not an "off-label" use. (Plaintiffs' Concise Statement of Material Facts, ¶¶63,68). Despite its repeated attempts to do so, PLIVA cannot simple swirl facts out of thin air like so much cotton candy. There is no support for the assertions PLIVA makes in regard to O.R.S. §30.910.

G. Plaintiffs Can Establish Both General And Specific Causation

With regard to general causation, PLIVA erroneously contends that Plaintiffs have only Dr. Seeman's testimony to prove general causation and that Dr. Seeman's testimony is inadmissible. Nothing could be further from the truth. To begin, it is **undisputed** that metoclopramide can cause tardive dyskinesia. Aside from the testimony of every single physician deposed in this case, PLIVA's own experts acknowledge that metoclopramide causes tardive dyskinesia. (*See* Concise Statement of Material Facts, ¶32). There is no credibility in

PLIVA's argument.

Further, all of Mrs. Phelps' treating neurologists hold the opinion that she suffers from tardive dyskinesia caused by metoclopramide. (Concise Statement of Material Facts, ¶¶20,22,25). Dr. Chamberlain, Mrs. Phelps' gastroenterologist, also stated that her abnormal movements appeared to be tardive dyskinesia. In short, every physician providing testimony in this case who has seen and examined Mrs. Phelps believes that she has tardive dyskinesia. Those that are qualified to make the determination believe that her tardive dyskinesia was caused by metoclopramide. Faced with an unwaivering consensus, PLIVA attempts to direct doubt towards the differential diagnosis performed by Plaintiff's physicians. This argument also lacks merit – Mrs. Phelps' diagnosis of metoclopramide-induced tardive dyskinesia rests on solid ground. *See McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092, 1104 (D. Or. 2010); *Clausen v. M/V New Carissa*, 339 F.3d 1049, 1058-59 (9th Cir.2003); *Mattis v. Carlon Elec. Prods.*, 295 F.3d 856, 861 (8th Cir.2002).

H. Plaintiffs' Punitive Damages Claim Is Viable

PLIVA claims that Plaintiffs' punitive damages claim must be dismissed because such a claim is preempted by O.R.S. §30.927. Again PLIVA misses the point. The very text of the statute cited by PLIVA belies the fault in the argument it advances. In particular, §30.927 provides that a manufacturer of a drug shall not be held liable for punitive damages "if the drug alleged to have caused the harm **was manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal Food and Drug Administration** under the Federal Foood, Drug and Cosmetic Act or the Public Health Service Act."

PLIVA's argument that it is exempt from punitive damages by virtue of O.R.S. §30.927 verges on absurd. The very reason that this Court has found certain claims to survive the Supreme Court's decision in *PLIVA, Inc. v. Mensing* is that PLIVA's metoclopramide **was not labeled in accordance with its approval by the FDA.** As the Supreme Court made clear in its decision, in order to market a generic drug, a manufacturer must ensure that its label matches the RLD **at all times.** *See Mensing*, 131 S.Ct. 2567, 2578, citing 21 C.F.R. 314.150(b)(10) ("Federal law, however, demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels."). PLIVA's argument that Plaintiffs' punitive damages claim must be dismissed has no merit.

III. CONCLUSION

For those reasons set out in the above memorandum, PLIVA's Motion for Summary Judgment should be DENIED.

Respectfully submitted this 2nd day of August, 2012,

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CERTIFICATE OF COMPLIANCE

This brief complies with the applicable word-count limitation under LR 7-2(b), 26-3(b), 54-1(c), or 54-3(e) because it contains 4,835 words, including headings, footnotes, and quotations, but excluding the caption, table of contents, table of authorities, signature block, and any certificates of counsel.

___/s/ *Terrence J. Donahue, Jr.*___
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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was filed electronically on July 9, 2012, and is available for viewing and downloading from the ECF system. A notice of electronic filing was sent to the following counsel of record:

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